

In the Specification:

Please delete paragraph [0036] of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0036] Referring to Figure 2, integrated device 10 has a lancet ejection lever 36, a clear protective cap 38, and a strip return and cap removal lever 40. Disposable electrochemical test strip 42 with side fill channels 44 is shown in the loading position. The construction and manual use of a side-file test strip 42 is fully described in U.S. Patent 6,338,790 issued on January 15, 2002 to TheraSense, Inc., and U.S. application number 09/434,026, filed November 9, 1999, both incorporated herein by reference. Preferably, an existing test strip, such as the FreeStyle™ brand test strip developed and marketed by TheraSense, Inc., is used with the present invention rather than a ~~propriety~~ proprietary format designed especially for the integrated device. Advantages to using existing test strips include utilizing existing research and development, manufacturing, distribution, and inventory systems and having larger economies of scale, thereby allowing for a lower cost test strip. Also, a large user base of patients are already familiar with the existing strips, and if they desire, can alternately use the same strips in existing manual meters and in the automatic device.

Please delete paragraph [0046] of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0046] Referring to Figures 7A, 7B and 7C, alternate embodiments of lancets and caps are shown. Another factor that affects the overall size of the lancing mechanism is the length of the lancet itself. Traditional disposable lancets, such as shown in Figure 3, have an elongate body 48 and a short cap 51. In order to reduce the profile of device head 34, a shortened lancet 76 can be used that is just long enough to engage lancet holder 68 (shown in Figure 6[.]). This short length might make the lancet difficult for the user to handle

and install, so the protective cap 78 (that is removed before use) should be made much larger than usual to aid handling. Cap 78 may be an integrally molded, pull-off tab such as shown in Figure 7A, or may be a hollow cap 80 with large handle molded separately or in the same cavity as lancet 76 and placed over lancet 76 after molding, such as shown in Figure 7B. A hollow cup or solid "pin cushion" type area 82 can be provided at the opposite end of cap 78, as shown in Figure 7A, to cover the sharp during removal from the device and disposal.

Please delete paragraph [0054] of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0054] The mechanism may use a linear plunger to eject the lancet (pushing in the downward direction in Figure 8), or a wedge that bears between some feature on the lancet and the plunger body. For instance, to further reduce the height of plunger mechanism 91, a wedge-shaped eject lever could extend perpendicularly into the plane of Figure 8 and contact rear tapered edge 100 to urge lancet 76 downward and out of device 10. Preferably, an interlock mechanism is incorporated so that lancet 76 cannot be ejected while cap 38 is still in place. Alternatively, the ejection lever can be located inside cap 38 to achieve this same result.

Please delete paragraph [0063] of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0063] Other strip angles and trajectories can be alternatively used, keeping in mind that strip fill performance is improved when the strip approaches the target sample from the side. Also, good machine design practice dictates that the maximum pressure angle (the angle between a line drawn from the axis of rotation to the point of contact, and a line orthogonal to the cam surface at the point of contact) be no more than 30°. In other alternative embodiments, the entire strip need not be moved. For instance, the

proximal end of strip 42 can be held stationary while the distal end is deflected away from and/or toward droplet 104 with cams, rollers, guides or other suitable devices. Or, as shown in Figures 16A, 16B, 17A, 17B, or 18, the strip can be translated in a vertical or inclined line and the squeegee action can be accomplished by a compliant member such as a leaf spring or compression spring. Alternatively, the distal end of strip 42 may follow a helical path as the proximal end is simultaneously lowered and rotated (not shown[.]).

Please delete paragraph [0068] of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0068] In the preferred embodiment of integrated device 10, a processor-based electro-mechanical system controls the amount of time that elapses between firing of the lancet and the approach of test strip 42 to the test site. Patients who bleed easily can adjust this duration to be relatively short (for example 5 seconds) and those who bleed slowly can adjust it to be longer (for example 20 seconds[.]). Alternatively, a purely mechanical system for this adjustable delay may be used.

Please delete paragraph [0074] of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0074] With a fresh lancet 46 and test strip 42 loaded, integrated device 10 is cocked by pulling up on cocking collar 22, and then placed over the test site on the patient, with recess 52 of cap 38 resting on the skin. Preferred testing sites include the forearm, upper arm, outer thigh, calf, and around the base of the thumb. Once device 10 is positioned, the patient presses actuator button 20 which causes lancet 46 to drive downward penetrating the skin and then retract. After a predetermined and preferably user-settable delay for allowing blood to emerge from the lancing site on the skin, test strip 42 is brought down along an arcuate path into contact with the blood sample. The patient holds device 10 in this position until device 10 emits an audible and/or

visual indication that a sufficient amount of blood has been drawn into fill channel 44 of test strip 42 (detected by electrical measurements on strip 42[.]). Device 10 then performs the appropriate measurements on the electrochemical process within test strip 42, and when complete displays the result on LCD 16. Further manipulation of data or settings can be performed by pressing function buttons 12 and 14.

Please delete paragraph [0077] of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0077] Referring to Figure 14, a scheme for encoding test strips 42 with fill channel 44 location data is disclosed. In the manufacture of disposable test strips such as for testing blood glucose, it can be difficult to produce large quantities of strips 42 all having their fill channels 44 located a predetermined distance from an end of the strip 42 within a narrow tolerance. Since the blood samples 104 to be acquired by strips 42 are becoming quite small (e.g. 0.050 inches in diameter), a wide fill channel location tolerance can make it difficult or impossible for an integrated testing device to automatically align the test strip 42 with the blood droplet [[44]] 104. This problem can be solved by providing integrated device 10 with a motor or other prime mover to position the strip 42 longitudinally, and encoding the fill channel location for each strip 42 in a calibration code specific to that strip or batch of strips. When the calibration code is entered by the user or detected from strip 42 automatically, device 10 can then position the test strip 42 accordingly.

Please delete paragraph [0080] of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0080] Referring to Figure 15, an alternative method for firing lancing mechanism or strip delivery mechanism is disclosed. In the preferred embodiment of integrated device 10, the lancing or plunger mechanism 91 (shown schematically in Figure 8) is cocked by pulling up on cocking collar

22, and fired by pressing actuator button 20 (both shown in Figure 1[.]). The test strip moving mechanism 160 (shown in Figures 12 and 13), on the other hand, is not directly actuated by the user but is instead controlled by the device's microprocessor 152, which ensures a suitable delay between lancet firing and test strip movement as described above. An electric solenoid can be employed between microprocessor 152 and release pin 138, but given the typical force required to move pin 138, the size of the solenoid and the batteries required to drive it is unwieldy. Since pin 138 does not need to be extracted with great speed, a motor and lead screw arrangement can be employed instead of a solenoid, but this introduces complexity, cost and reliability issues. To overcome the above drawbacks, a shape memory alloy (SMA) wire can be used to drive release pin 138.

Please delete paragraph [0083] of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0083] The preferred embodiment of integrated device 10 will have a specified operating temperature range, for example between 0 and 40 degrees Celsius. To ensure that wire 162 reaches the proper temperature to contract and operate the release mechanism properly when device 10 is anywhere within the specified temperature range, conventional control circuitry would always apply the maximum electrical current required to heat the wire from the bottom of the temperature range to the temperature required for wire contraction. However, device 10 would typically not be operated at the bottom of the predetermined operating range, so much of the current applied to wire 162 during each use would merely be drained from the device's batteries without providing any benefit. To overcome this drawback, device 10 should utilize a temperature sensor (which can also be used for other testing functions) and a current switching circuit that supplies only enough current to elevate wire 162 from the ambient temperature to the contracting temperature. Rather than supplying a constantly decaying current from a charged capacitor to wire 162, the device's microprocessor can be configured to sense the ambient

temperature and control a switch with one of its outputs to provide a series of pulses of current to wire 162 to cause its contraction. As ambient temperature decreases, the microprocessor provides pulses of longer duration, approaching a constant source of current as the ambient temperature approaches the bottom of the predetermined operating range. Alternatively, rather than pulsing the current, the duration of the current can be controlled based on the ambient temperature (i.e. a shorter duration for a higher ambient temperature[.]). By employing this inventive circuitry, smaller batteries can be used and/or longer battery life can be achieved, thereby making device 10 more compact and less expensive.